REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 8-20 will be pending in the application subsequent to entry of this Amendment.

The originally filed claims have been amended in order to more particularly point out and distinctly claim that which applicants regard as their invention and to address issues of claim clarity raised on pages 2-3 of the Official Action. New claims 8-14 correspond generally with previous claims 1-7. New claims 15-20 correspond generally to previous claims 1 and 3-7 and specifically they omit the use of a dsRNA during the initial stage of therapy. These claims also refer to an anti-retroviral agent and thus exclude the use of a dsRNA in steps 1 and 4.

This application relates to the use of highly active anti-retroviral therapy (HAART) followed with Strategic Therapeutic Intervention (STI). HAART is a treatment so rigorous that significant cumulative toxicities develop, including hepatitis and pancreatitis. As HAART continues and the HIV load decreases - but before cumulative toxicities develop - the anti-retroviral therapy is stopped (interrupted). During this time a dsRNA, acting both an anti-viral and immune-stimulating agent which serves to improve the patient's immune system, is administered and is continued for a period of time. If and when the HIV load increases the HAART treatment is resumed.

In the Official Action claims 1, 2 and 7 are rejected as being anticipated by U.S. patent 4,950,652 ('652) to William A. Carter, one of the inventors herein. Applicants disagree and now provide the information requested by the examiner. The Official Action on page 5, first full paragraph, acknowledges that the '652 patent "is silent regarding the sequential order of treatment of HIV with the antiviral agent in combination with the dsRNA. However, the burden of establishing whether the prior art method discontinued antiviral therapy then resumed antiviral treatment falls to applicant" citing §2112.01 of the MPEP. Similar comments are made at the bottom of page 5 of the Official Action.

With the examiner's comments in mind, attached herewith is the Declaration of William A. Carter, M.D., the inventor of the cited reference (as well as many other U.S. and foreign patents) addressing the examiner's comments and questions directly. Dr. Carter clearly distinguishes the therapeutic regimen of the present application with procedures employed in the early 1990s such as evidenced by his '652 patent, emphasizing that the form of therapy

employed in the present application "differs significantly from that practiced in the late 80's and early 90's in which anti-viral therapy once instituted was continued for long periods of time and there was no strategic or other kind of planned 'interruption' or 'intervention' in the regimen of therapy"; *see* item 8 of the Declaration.

Dr. Carter also distinguishes dsRNA therapy from various types of anti-retroviral treatments; *see* item 9 of the Declaration.

This formation directly responds to the examiner's invitation and establishes the prior art method did not discontinue therapy with the dsRNA.

The Official Action also rejects as "obvious" all of the seven originally filed claims on the basis of the Carter '652 patent and two additional journal articles, one to Ruiz and the other to Schlomo et al. Having explained how the claimed invention differs from the '652 patent, this explanation also distinguishes the claimed regimen when the '652 patent is considered in combination with these two journal articles.

In fact, it is quite surprising that dsRNA is of therapeutic benefit during at least the strategic intervention portion of the HAART/STI protocol, *see*, for example, the review article "Structured Treatment Interruptions – New Findings" of Benson in the August/September 2006 issue of Topics in HIV Medicine where the author of this review study notes "On balance, data from these studies indicate that STI is associated with worse immunologic, virologic, and clinical outcomes than continuous antiretroviral therapy."

Similarly, Oxenius et al in Proceedings of the National Academy of Science comments "Overall, these data indicate that STI-induced quantitative boosting of HIV-specific cellular immunity was not associated with substantial change in viral replication and that STI was largely restoring pretherapy $CD8^+$ T cell responses in patients with established infection."

See also Lawrence et al, "Structured Treatment Interruption in Patients with Multidrug-Resistant Human Immunodeficiency Virus" in the New England Journal of Medicine, 2003, in which the authors observe "In patients infected with multidrug-resistant HIV, structured interruption of treatment was associated with greater progression of disease and did not confer immunologic or virologic benefits or improve the overall quality of life."

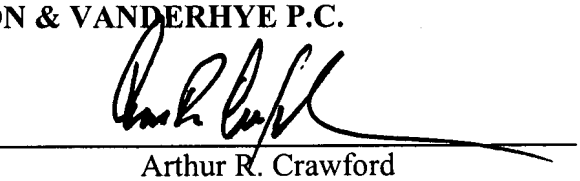
The three Journal articles mentioned above are submitted herewith in an Information Disclosure Statement primarily for completion of the record as the dates of publication fall subsequent to the filing date of the underlying PCT application and/or the 2001 provisional application from which benefit of priority is claimed.

The point here is that unlike Ruiz and Schlomo, others have found the HAART/STI procedure to be less than successful if not generally unsuitable. Surprisingly, applicants are able to render this approach of treating HIV in a novel and therapeutically beneficial way by administering during the period of therapeutic intervention the immune-stimulating dsRNA.

For the above reasons it is submitted that the claims of this application as presented above define both novel and inventive subject matter. Reconsideration and favorable action are solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

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